

5. 510(K) SUMMARY

1. SUBMITTER:

SEP 18 2007

NDO Surgical, Inc.
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Contact: John J. Vozella, V.P. Regulatory/Clinical/QA

Date Prepared: June 1, 2007

2. DEVICE:

Trade Name: Endoscopic Plication System; Plicator™

Common Name: Endoscope accessory

Classification Name: Endoscope and accessories

Class: II

3. PREDICATE DEVICE:

NDO Surgical Endoscopic Plication System (K023234, K032820)

4. DEVICE DESCRIPTION:

The NDO Surgical Endoscopic Plication System (EPS) is a device that deploys a suture-based implant in the stomach near the Gastroesophageal Junction thereby creating a full thickness plication of the gastric cardia for the treatment of Gastroesophageal Reflux Disease (GERD). The EPS consists of three procedural components: the Plicator instrument, the Plicator retractor and the Plicator implant cartridge. The implant cartridge and retractor are loaded onto the instrument and the instrument is then passed transorally into the stomach to create the plication. The Plicator instrument's shaft, which comes into contact with the patient, is made of polyurethane. The retractor is made of surgical grade stainless steel, with a polycarbonate sheath. The implant is comprised of two titanium retention bridges, 2.0 polypropylene suture and two ePTFE pledges. The implant is housed in a disposable cartridge. Once the Plicator instrument has been introduced into the stomach, the retractor is engaged into the gastric cardia and the tissue is retracted into the arms of the instrument. The arms of the instrument are closed and the implant is deployed, creating a full thickness, serosa-to-serosa plication.

5. INTENDED USE:

The NDO Endoscopic Plication System (EPS) is indicated for the treatment of the symptoms of chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

6. COMPARISON OF CHARACTERISTICS:

The proposed Endoscopic Plication System (EPS), is similar in design and materials and identical in fundamental operating principles and intended use to the predicate EPS device (K023234, K032820).

The changes made are to the Plicator™ instrument, implant cartridge, implant, accessories and labeling.

The Plicator instrument is modified as compared to the predicate (K032820) device by:

- Changing the design of the instrument leak test port to more reliably prevent the accidental introduction of moisture to the interior of the instrument during cleaning and high level disinfection.
- Changing the dimensions of the instrument arms to accommodate a revised implant cartridge design.
- Changing the instrument shaft material from polyvinyl chloride coated with parylene to polyurethane to improve durability and puncture resistance.
- Adding printed directional markings to the instrument shaft and controls to clarify operation of the instrument / user interface.
- Changing the ink used to print the instrument shaft to assure compatibility with a screen printing process.
- Simplifying the design of certain mechanical elements of the instrument (e.g. transmission assembly, deploy button, strain relief, locking mechanism and cables) to promote ease of assembly and improved instrument reliability.

The Plicator implant cartridge is modified compared to the predicate (K032820) device by:

- Extending the length of the titanium needles to permit them to be inserted deeper into the implant cartridge chassis and bending the needles to promote reliable alignment with the implant plegget's holes during implant deployment.
- Modifying the dimensions of the implant cartridge chassis to accommodate longer needles and changing the angle of the implant cartridge ramp and the ramp dimensions to increase needle break reliability during implant deployment.
- Changing the implant cartridge material to a stiffer material.

The Plicator implant has been modified by:

- Changing the dimensions of the holes in the ePTFE pledges to accommodate changing needle entry angles during implant deployment.

All other aspects of the Plicator implant subject to this submission remain identical to the predicate implant (**K032820**).

The Plicator retractor referenced in this submission is identical to the predicate EPS retractor (**K032820**), except that the handle has been slightly modified to permit the use of an “off-the-shelf” component design.

EPS labeling has been modified to:

- Include additional precautions and potential complications based on field and clinical experience with the predicate device.
- Update directions for use to describe the technique associated with the placement of multiple Plicator™ implants as opposed to a single Plicator implant as was the case with the predicate device.
- Update cleaning and high level disinfection instructions.

The indications for use presented in this submission are identical to the predicate EPS indications for use.

The following accessories have been modified or added to the Endoscopic Plication System (EPS):

- Leak test port caps (Olympus, Pentax and Fujinon) and a leak test port seal have been added as accessories to the instrument to further limit the potential for accidental moisture introduction to the instrument during cleaning and high level disinfection activities.
- Endoscopic scissors have been added as an EPS accessory to permit cutting of sutures in the unlikely event that improper deployment of a Plicator implant causes the implant to be tethered by suture to the Plicator instrument.

Scope channel and retractor channel seals and cleaning brushes and other accessories remain unchanged from the predicate EPS (**K032820**) accessories.

7. PERFORMANCE DATA:

Bench testing of the modified Plicator instrument, implant cartridge, implant and accessories demonstrated that:

- The modified leak test port design, cap and seal reliably inhibit the ingress of moisture into the Plicator instrument during cleaning and high level disinfection.

- The modified Plicator instrument and implant cartridge are compatible and reliably deploy Plicator implants.

Biocompatibility testing confirmed acceptable and equivalent biocompatibility profiles of patient contact materials used in the modified Plicator instrument and implant cartridge as compared to materials present in the predicate instrument and implant cartridge.

Simulated use testing demonstrated the feasibility of safely deploying multiple, serially placed, Plicator implants.

Clinical testing demonstrated that serial placement of multiple, Plicator implants to form multiple, serial, full-thickness plications of the gastric cardia in close proximity to the anterior gastroesophageal junction safely and effectively treats the symptoms of gastroesophageal reflux disease.

8. CONCLUSION:

The modified Endoscopic Plication System (EPS) referenced in this submission is equivalent in technology, method of operation and intended use to the predicate EPS.

The serial placement of multiple Plicator implants to form multiple, serial, full-thickness plications of the gastric cardia in close proximity to the anterior gastroesophageal junction is equivalent in safety and effectiveness to single Plicator implant placement for the treatment of symptomatic gastroesophageal reflux disease.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 18 2007

Mr. John J. Vozella
V.P. RA/Clinical/QA
NDO Surgical, Inc.
125 High Street, Suite 7
MANSFIELD MA 02048

Re: K071553

Trade/Device Name: Endoscopic Plication System; EPS; Plicator™
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODE
Dated: September 4, 2007
Received: September 5, 2007

Dear Mr. Vozella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|----------------|----------------------------------|--------------|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 071553

Device Name: Endoscopic Plication System; EPS; Plicator™

Indications for Use: The NDO EPS System (Plicator™) is indicated for the treatment of the symptoms of chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

Prescription Use X
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K 071553